

K092389

## 5. 510(k) Summary

### 1. Company Identification

SUZUKEN CO, LTD.

OCT 13 2009

8 Higashikataha-machi, Higashi Nagoya, Aichi, JAPAN 46191

Tel: +81-52-950-6327

Fax: +81-52-950-7440

### 2. Official Correspondent

Motokazu Takeuchi (Mr.)

Senior Manager

### 3. Date of Submission

August 4, 2009

### 4. Device Trade name

Disposal ECG electrodes, Model Easyrode

### 5. Common/Usual Name

Electrocardiograph Electrode

### 6. Classification Number

Electrocardiograph Electrode classified in Class II per 21 CFR 870.2360, DRX

### 7. Predicate Device

Manufacturer : 3M Health Care

Device Name : 3M Red Dot 2560 Monitoring Electrode with Foam Tape and  
Stickey Gel

510(k) No. : K970796

## **8. Description of the Device**

Easyrode is a self-adhesive, non-sterile, single use disposable electorode which includes a silver/silver chloride sensing element and conductive gel.

These electrodes include a pressure sensitive adhesive non-woven tape which hold the conductive elements of the electrodes in place on the patient's skin for short or long term ECG procedures.

## **9. Intended Use**

The Easyrode is intended for use in ECG Monitoring. The Easyrode can be used in all ECG applications where standard ECG monitoring electrodes are used. This electrode can be used for short term and long term (2 Days) monitoring.

## **10. Technological Characteristics**

### **Intended for Use**

Easyrode: Used for short time and long time (up to 2day)

Predicate device: Used for short time and long time (2day)

Easyrode is used for 2day and below.

### **Material:**

Easyrode: Non-woven tape

Predicate device: Foam tape

Non-woven is allow air pass through easily than foam.

That means non-woven is more adhesive to patient skin

Comparison table of the principal characteristics of 2 devices is shown in the 9.  
Substantial Equivalence Discussions.

## **11. Conclusion**

The results of these measurements demonstrated that the Easyrode is as safe, as effective, and performs as well as the predicate device.



## DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

AUG 26 2011

Suzuken Co., Ltd  
c/o Mr. Koji Kubo  
Cosmos Corporation  
3F, 2-17-6 Akebono-cho  
Tachikawa-shi, Tokyo 190-0012  
JAPAN

Re: K092389

Trade/Device Name: Disposal ECG Electrodes, Model Easyrode  
Regulation Number: 21 CFR 870.2360  
Regulation Name: Electrocardiograph electrode  
Regulatory Class: II (two)  
Product Code: DRX  
Dated: July 31, 2009  
Received: August 5, 2009

Dear Mr. Kubo:

This letter corrects our substantially equivalent letter of October 13, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

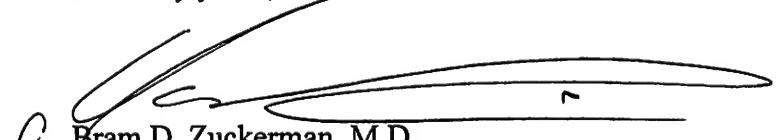
found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



*[Handwritten signature of Bram D. Zuckerman, M.D.]*

Br  
Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(K) Number (if known)

*K092389*

Device Name: Disposal ECG electrodes, Model Easyrode

Indications For Use :

The Easyrode is intended for use in ECG Monitoring. The Easyrode can be used in all ECG applications where standard ECG monitoring electrodes are used. This electrode can be used for short term and long term (2 Days) monitoring.

Prescription Use X

AND / OR Over-The Counter Use \_\_\_\_\_

(Per 21 CFR 801.109 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*W.M. St.*

(Division Sign-Off)  
Division of Cardiovascular Devices

510(k) Number *K092389*